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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,706	01/23/2006	Shing Yue Chan	CU60405	7430

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1611	

NOTIFICATION DATE	DELIVERY MODE
12/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,706	CHAN ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11-22 and 25-34* is/are withdrawn from consideration.

5)☒ Claim(s) *1-10,23 and 24* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 09/24/2009, and IDS filed 01/23/2006.

Claims 1-34 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of invention I, claims 1-10, 23, and 24, in the reply filed on 09/24/2009 is acknowledged. The traversal is on the ground(s) that the inventions have the same technical features. This is not found persuasive because each invention is independent or distinct from the others. Each invention has distinct structure and independent agent that is not required by the other inventions. Because inventions are distinct, there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present six distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-22, 25-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/24/2009.

Claims 1-10, 23 and d24 are included in the prosecution.

Specification

3. The use of the trademark “Eudragit” has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-10, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0068376, IDS filed 01/23/2006) in view of Lerner et al. (US 6,197,331, currently listed on PTO 892), as evident by the article by Lamosa et al. ("Design of Microencapsulated Chitosan Microspheres for Colonic Drug Delivery", currently listed on PTO 892).

Applicant Claims

Applicants' claim 1 is directed to an orally dissolving film composition comprising:

a) an enteric polymer;

b) at least one alkaline buffering agent; and

c) at least one active agent.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Chen teaches dosage form of nicotine delivery system in the form of mucoadhesive film that dissolve when applied intraorally to release nicotine which is absorbed through the oral mucosa to the systemic circulation. The mucoadhesive film is used to assist smoking cessation and for providing substitutes for smoking (abstract). The film comprises nicotine, buffering agents, polymer and plasticizer (paragraphs 0011, 0062). The film can be monolayer, or bilayer in which one layer contains nicotine and the other layer contains buffering agent (paragraph 0012). The nicotine can be salts such as hydrochloride, dihydrochloride, sulfate, zinc chloride, or salicylate (paragraph

0014). The buffering agents include sodium carbonate or bicarbonate, and sodium and potassium phosphate (paragraph 0015). The polymer includes polyacrylic acid polymers (paragraph 0059).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Chen teaches mucoadhesive film and suggests polyacrylic acid polymers, however, the reference does not explicitly teach enteric polymers. Chen does not teach nicotine oil as claimed by claim 8.

Lerner teaches composition in form of patch for applying pharmaceutical active agent to the oral cavity to release the agent for predetermined period at predetermined concentration for systemic or local action (abstract; col.7, lines 50-51). The composition provides oral release of pharmaceutical agent and buccal absorption resulting in rapid systemic delivery of the released pharmaceutical (col.7, lines 1-4). The composition is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged (col.7, lines 8-11, 18-19). The composition comprising pH buffering agent (col.11, lines 54-65), and polymer including neutral copolymer based on acrylic acid ester and methacrylic acid, with Eudragit L100 most preferred (col.11, lines 1-23; claim 4). Eudragit L 100 is enteric pH sensitive polymer as evident by Lamosa.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an oral dissolvable film comprising nicotine, buffering agent and polyacrylic polymer to release nicotine in the oral cavity as taught by Chen, and replace the polyacrylic acid polymer with enteric polymer, specially neutral copolymer of methacrylic acid and acrylic acid esters as taught by Lender. One would have been motivated to do so because Lender teaches that enteric polymers, specially neutral copolymer of methacrylic acid and acrylic acid esters are suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged, and further suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. One would reasonably expect formulating oral dissolvable film comprising nicotine, buffering agent and enteric polymer to release nicotine in the oral cavity to be absorbed from the buccal mucosa to provide rapid systemic effect, and meanwhile the film is comfortable in the mouth of the user.

Regarding nicotine oil as claimed by claim 8, applicants failed to show unexpected results obtained from nicotine oil over the use of nicotine salts disclosed by Chen et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Chen and Lender as evident by Lamosa and further in view of Adusumili et al. (US 2004/0037879, currently recited on PTO 892).

The combined teachings of Chen and Lender as evident by Lamosa are previously discussed as set forth in this office action.

The references, however, do not teach nicotine oil in particular as claimed by claim 8.

Adusumili teaches oral dosage formulations comprising nicotine active to alleviate some of the nicotine withdrawal symptoms that a person may experience during attempts to quit smoking (abstract). The nicotine active may be selected from a wide variety of nicotine sources such as pharmaceutically acceptable salts of nicotine. Non-limiting examples of such salts include nicotine monotartrate, bitartrate, hydrochloride, dihydrochloride, sulfate, nicotine zinc chloride monohydrate, nicotine salicylate, nicotine oil and nicotine polacrilex (paragraph 0032).

Adusumili teaches the equivalency between nicotine salts and nicotine oil in a process for alleviating nicotine withdrawal symptoms that a person may experience during attempts to quit smoking.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an oral dissolvable film comprising nicotine salts, buffering agent and enteric polymer to assist smoking cessation as taught by the combination of Chen and Lender, and further replace nicotine salt with nicotine oil

taught by Adusumili. One would have been motivated to do so because Adusumili teaches the equivalency between nicotine salts and nicotine oil in process for alleviating nicotine withdrawal symptoms. One would reasonably expect formulating an oral dissolvable film comprising nicotine oil, buffering agent and enteric polymer wherein the film assists to alleviate nicotine withdrawal symptoms that a person may experience during attempts to quit smoking.

Correspondence

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611